

PATENT

Case Docket No. OPTIS.039A

Date: December 21, 2004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Bernhard B. Sterling et al.
Appl. No. : 10/055,875
Filed : January 21, 2002
For : REAGENT-LESS WHOLE-
BLOOD GLUCOSE METER
Group Art Unit : 2877
Class/Sub-Class : 356-039000
Examiner : Punnoose, Roy M.

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

December 21, 2004

(Date)

Mark Kertz

Mark J. Kertz, Reg. No. 43,711

TRANSMITTAL LETTER

MAIL STOP ISSUE FEE

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing is the Issue Fee for the above-identified application:

- (X) Form PTOL-85.
- (X) A check in the amount of \$50 to cover the issue fee and advanced order of copies is enclosed.
- (X) A check in the amount of \$130 to cover the fee for Petition.
- (X) Comments on Statements of Reasons for Allowance in 3 pages.
- (X) Summary of Personal Interview Conducted on October 14, 2004 in 2 pages.
- (X) Summary of Telephonic Interview Conducted on October 26, 2004 in 2 pages.
- (X) Petition to Correct Inventorship in 2 pages.
- (X) Establishment of Right of Assignee to Take Action and Consent of Assignee in 2 pages.

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- (X) Statement of Peng Zheng in 2 pages.
- (X) Statement of W. Dale Hall in 2 pages.
- (X) The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 11-1410.
- (X) Return prepaid postcard.

Mark Kertz

Mark J. Kertz

Registration No. 43,711

Attorney of Record

Customer No. 20,995

(949) 760-0404



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Examiner	:	Roy Punnoose
Art Unit	:	2877

COMMENTS ON STATEMENTS OF REASONS FOR ALLOWANCE

United States Patent and Trademark Office
P.O. Box 1450
Arlington, VA 22313-1450

Dear Sir:

In response to the Examiner's statements of reasons for allowance, which statements were made in the Notices of Allowability mailed on November 12, 2004 and October 21, 2004, Applicant makes the following comments:

Applicant respectfully objects to the Examiner's statements to the extent that he has paraphrased independent Claim 95 when characterizing the allowable subject matter. Although Claim 95 may cover the subject matter recited by the Examiner in his reasons for allowance, Applicant emphasizes that the scope of Claim 95 is determined by its terms and not the Examiner's characterization thereof. As allowed, Claim 95 recites:

95. A method for determining the concentration of an analyte in a patient, in no particular sequence, comprising:

providing an optical detection system which is portable and sized and configured to be small enough to fit in the palm or pocket of the patient, the detection system comprising a housing, at least one source of electromagnetic radiation, at least one detector, an optical path extending between the source and the detector, and a filtering system in the optical path, the filtering system configured to allow passage of at least one

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of the following wavelengths emitted by the source: about 4.2 μm , about 5.25 μm , about 6.12 μm , about 7.4 μm , about 8.0 μm , about 8.45 μm , about 9.25 μm , about 9.65 μm , about 10.4 μm , about 12.2 μm ;

providing a disposable sample element comprising a reagentless sample cell and an opening, the sample cell and the opening being in fluid communication through a sample supply passage, the sample cell being formed at least in part by at least one window constructed from a material selected from the group consisting of polyethylene and polypropylene;

installing the sample element into the housing of the optical detection system;

positioning the sample element such that the sample cell is located at least partially in the optical path and such that the opening of the sample element is exposed outside the housing;

extracting a sample of biological fluid from the patient;

contacting the opening of the sample element with the sample, such that a portion of the sample is drawn into the sample element;

transporting the sample portion from the opening to the sample cell through the supply passage via capillary action;

transmitting a calibration beam of radiation from the source through the sample element, but not through the sample portion, such that a calibration signal is generated by the optical detection system, the sample element having a first window separation where the calibration beam passes through the sample element;

transmitting an analyte beam of radiation from the source through the sample element and through the sample portion, such that an analyte signal is generated by the optical detection system, the sample element having a second window separation where the calibration beam passes through the sample element, the second window separation being different from the first window separation; and

correcting the analyte signal using the calibration signal to substantially eliminate the absorption of the sample element.

Similarly, Applicant respectfully objects to the Examiner's statements to the extent that he has paraphrased independent Claim 105 when characterizing the allowable subject matter. Although Claim 105 may cover the subject matter recited by the Examiner in his reasons for allowance, Applicant emphasizes that the scope of Claim 105 is determined by its terms and not the Examiner's characterization thereof.

Applicant also respectfully objects to the Examiner's statements to the extent that there is any implication that dependent Claims 96-104 and 106-113 are allowable only because they are dependent on allowable independent Claims 95 and 105, respectively. Dependent Claims 96-104 and 106-113 are allowable also because they recite further novel and non-obvious combinations of features or acts.

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If the Examiner has any questions, the Examiner is respectfully requested to telephone the undersigned Attorney.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

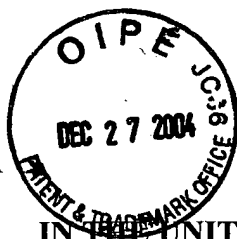
Dated: Dec. 21, 2004

By: Mark Kertz

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SUMMARY OF PERSONAL INTERVIEW CONDUCTED ON OCTOBER 14, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicant summarizes the personal interview conducted on October 14, 2004, as follows.

In Attendance

- | | |
|----------------------|---------------------------------------|
| 1) Exr. Roy Punnoose | 2) Exr. Gregory Toatley |
| 3) James R. Braig | 4) William B. Bunker, Reg. No. 29,365 |

Exhibits and/or Demonstrations

Components of one embodiment of the claimed apparatus.

Identification of Claims Discussed

95-113

Identification of Prior Art Discussed

Neufeld US 4,569,589; Poto US 5,795,543

Proposed Amendments

None.

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Principal Arguments and Other Matters

Mr. Braig reviewed the state of the art and the operation of the prior art of record, as well as an embodiment of the claimed method and apparatus. Mr. Bunker indicated that the prior art does not appear to teach, inter alia, calibration as claimed.

Results of Interview

Mr. Punnoose provisionally agreed that claims 95-113 defined over the prior art of record.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: Dec. 21, 2004

By: Mark J. Kertz

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SUMMARY OF TELEPHONIC INTERVIEW CONDUCTED ON OCTOBER 26, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicant summarizes the telephonic interview conducted on October 26, 2004, as follows.

In Attendance

1) Exr. Roy Punnoose 2) Mark J. Kertz, Reg. No. 43,711

Exhibits and/or Demonstrations

None.

Identification of Claims Discussed

51-61, 83-88

Identification of Prior Art Discussed

None.

Proposed Amendments

None.

Application No. : 10/055,875
Filed : January 21, 2002

Principal Arguments and Other Matters

None.

Results of Interview

Mr. Kertz agreed to cancellation of claims 51-61 and 83-88 to address informality under 37 C.F.R. § 1.121(c)(3) of amendment filed on October 4, 2004.

Respectfully submitted,
KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: Dec. 21, 2004

By: Mark Kertz
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